Message

From: Nathan Rose [nathan.rose@oxitec.com]

Sent: 3/31/2020 8:34:18 AM

To: Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Reynolds, Alan

[Reynolds.Alan@epa.gov]; Matthews, Keith [KMatthews@wiley.law]

CC: Brad Shurdut [bshurdut@gmail.com]; Kevin Gorman [Kevin.Gorman@oxitec.com]

Subject: RE: Oxitec application

Hi Mike, Alan and Eric

Thanks again for a constructive call yesterday. Let me know whether another brief call today will be helpful – our schedules are pretty flexible.

Kind regards Nathan

From: Bohnenblust, Eric < Bohnenblust. Eric@epa.gov>

Sent: 27 March 2020 18:53

To: Nathan Rose <nathan.rose@oxitec.com>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan

<Reynolds.Alan@epa.gov>; Matthews, Keith <KMatthews@wiley.law>

Subject: RE: Oxitec application

Nathan,

Great, I don't know for certain if Bob will be on the call at this time. He is aware we are having a call and I'll let him know when it is.

Thanks for confirming the 9 am time, call-in info will be the usual number

202-991-0477

Access code 2209646

Eric Bohnenblust, Ph.D

Senior Biologist

Emerging Technologies Branch (ETB)

Biopesticides and Pollution Prevention Division (BPPD)

Phone: 703-347-0426

Email: Bohnenblust.eric@epa.gov

From: Nathan Rose <nathan.rose@oxitec.com>

Sent: Friday, March 27, 2020 2:49 PM

To: Bohnenblust, Eric <<u>Bohnenblust, Eric@epa.gov</u>>; Mendelsohn, Mike <<u>Mendelsohn, Mike@epa.gov</u>>; Reynolds, Alan@epa.gov>; Matthews, Keith <<u>KMatthews@wiley.law</u>>

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Cc: Brad Shurdut bshurdut@gmail.com; Kevin Gorman Kevin.Gorman@oxitec.com>

Subject: RE: Oxitec application

Hi Eric

Thanks for the quick response! We can do Monday 9am – let me know if the usual dial-in details will work. Will Bob McNally be joining too?

Best wishes

Nathan

From: Bohnenblust, Eric < Bohnenblust. Eric@epa.gov>

Sent: 27 March 2020 16:43

To: Nathan Rose < nathan.rose@oxitec.com >; Mendelsohn, Mike < Mendelsohn.Mike@epa.gov >; Reynolds, Alan

< Reynolds. Alan@epa.gov>; Matthews, Keith < KMatthews@wiley.law>

Cc: Brad Shurdut bshurdut@gmail.com; Kevin Gorman kevin.Gorman@oxitec.com>

Subject: RE: Oxitec application

Keith and Nathan,

Are you available Monday morning to discuss the PRIA date for the EUP application. We are available between 9 and 10 am. Let me know if 9 or 9:30 works better for you.

Thanks.

Eric Bohnenblust, Ph.D Senior Biologist Emerging Technologies Branch (ETB) Biopesticides and Pollution Prevention Division (BPPD)

Phone: 703-347-0426

Email: Bohnenblust.eric@epa.gov

From: Nathan Rose <nathan.rose@oxitec.com>

Sent: Friday, March 27, 2020 5:30 AM

To: Mendelsohn, Mike < Mendelsohn.Mike@epa.gov>; Bohnenblust, Eric < Bohnenblust.Eric@epa.gov>; McNally, Robert < Mcnally.Robert@epa.gov>; Reynolds, Alan < Reynolds.Alan@epa.gov>

Cc: Brad Shurdut

bshurdut@gmail.com; Kevin Gorman kevin.Gorman@oxitec.com; Matthews, Keith

< <u>KMatthews@wiley.law</u>> **Subject:** Oxitec application

Dear Bob, Mike, Alan and Eric

After our discussion on Monday regarding the Oxitec EUP PRIA date extension, I wanted to come back to you with our thoughts, having consulted the Oxitec management team.

The request to extend the PRIA date to Apr 30 was a big shock to us. A 30-day extension request when we are just days away from the finish-line seems unnecessarily long, in light of two previous PRIA extensions, and particularly because our teams have been working so closely together. We've been fielding answers rapidly and thoroughly to every question asked, and the types of questions now being asked are not technical stumbling blocks, but small refinements on protocols and such that need to be addressed prior to mosquito releases, not as part of the EUP approval itself.

This extension to 30 April could be very costly to us. Due to the last PRIA date change we lost one of the main components of our field trial in 2020. This new request for a delay of another full 30 days places us in jeopardy for the remaining trial we wanted to complete. If this new PRIA date spills over into May by even a few days, we will miss FDACS' only remaining 30-day window within which to approve our application at their 4 June meeting, which is the last meeting they'll hold that will allow us to proceed this year.

As we discussed on the call on Monday, is there anything that can be done to keep the PRIA date extension limited to 15 April 2020? Anything we can do to help facilitate that, let us know, and we're ready to discuss on a call any time that works for you.

Kind regards Nathan Nathan Rose, DPhil Head of Regulatory Affairs Oxitec Ltd 71 Innovation Drive, Milton Park OX14 4RQ, UK +44 (0) 1865 959 883

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